DEFENDANT SENORX, INC.'S ANSWER TO AMENDED COMPLAINT

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Defendant SenoRx, Inc. ("SenoRx"), through undersigned counsel, answers the Amended Complaint of Plaintiffs Hologic, Inc., Cytyc Corp., and Hologic L.P. (individually and collectively "Plaintiffs") as follows:

ANSWER TO NATURE OF THE ACTION

- SenoRx admits that in bringing this action, the Plaintiffs purport to seek damages 1. and injunctive relief arising out of SenoRx's alleged infringement of U.S. Patent Nos. 5,913,813; 6,413,204; and 6,482,142 (the "Patents-In-Suit"), and for alleged acts of false advertising. SenoRx denies that it infringes any valid, enforceable claim of any of the Patents-In-Suit, that it has engaged or does engage in false advertising, that the Plaintiffs are entitled to any damages or injunctive relief, and any and all other allegations set forth in paragraph 1 of the Amended Complaint.
- 2. On information and belief, SenoRx admits the allegations set forth in paragraph 2 of the Amended Complaint.
- On information and belief, SenoRx admits the allegations set forth in paragraph 3 3. of the Amended Complaint.
- On information and belief, SenoRx admits the allegations set forth in paragraph 4 4. of the Amended Complaint.
 - 5. SenoRx admits the allegations set forth in paragraph 5 of the Amended Complaint.

ANSWER TO JURISDICTION AND VENUE

The allegations of paragraph 6 of the Amended Complaint set forth legal 6. conclusions to which no response is required. To the extent that paragraph 6 of the Amended Complaint sets forth factual allegations to which a response is required, SenoRx admits that an action for infringement of a United States Patent may arise under 35 U.S.C. § 281, and that jurisdiction for such an action in this Court may be founded on 28 U.S.C. § 1338(a). SenoRx also admits that jurisdiction in this Court for an action under the Lanham Act, 15 U.S.C. § 1125(a), may be founded on 28 U.S.C. § 1331. SenoRx denies any and all other allegations set forth in paragraph 6 of the Amended Complaint.

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- 7. The allegations of paragraph 7 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent that paragraph 7 of the Amended Complaint sets forth factual allegations to which a response is required, SenoRx denies the allegations set forth in paragraph 7 of the Amended Complaint.
- 8. The allegations of paragraph 8 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent that paragraph 8 of the Amended Complaint sets forth factual allegations to which a response is required, SenoRx denies that it has committed, or intends to commit, acts of infringement or false advertising in this District, and any and all other allegations set forth in paragraph 8 of the Amended Complaint.

ANSWER TO INTRADISTRICT ASSIGNMENT

9. The allegations of paragraph 9 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent that paragraph 9 of the Amended Complaint sets forth factual allegations to which a response is required, SenoRx admits that this purports to be an intellectual property action that is subject to assignment on a District-wide basis pursuant to Civil Local Rule 3-2(c).

ANSWER TO BACKGROUND

- 10. SenoRx is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 10 of the Amended Complaint, and on that basis denies the allegations.
- 11. SenoRx is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 11 of the Amended Complaint, and on that basis denies the allegations.
- 12. SenoRx is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 12 of the Amended Complaint, and on that basis denies the allegations.
- 13. SenoRx admits that the term brachytherapy has been used to refer to radiation therapy in which the radiation source is in proximity to the tissue being treated. SenoRx is without knowledge or information sufficient to form a belief as to the truth of the other allegations

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allegations in that paragraph.

set forth in paragraph 13 of the Amended Complaint, and on that basis denies any and all other

- 14. SenoRx admits that a 510(k) Summary of Safety and Effectiveness, specifying a device name "MammoSiteTM Radiation Therapy System (RTS)," control number K011690, was date-stamped by the FDA on May 6, 2002. SenoRx denies any and all other allegations set forth in paragraph 14 of the Amended Complaint.
 - 15. SenoRx denies the allegations set fort in paragraph 15 of the Amended Complaint.
- 16. SenoRx admits that the Patents-In-Suit are the subject of this Amended Complaint, but denies that the patents were validly issued and denies any and all other allegations set forth in paragraph 16 of the Amended Complaint.
- SenoRx admits, on information and belief, that Cytyc Corp. acquired Proxima 17. Therapeutics ("Proxima") in 2005, and that Hologic, Inc. combined with Cytyc Corp. in 2007. SenoRx is without knowledge or information sufficient to form a belief as to the truth of the other allegations set forth in paragraph 17 of the Amended Complaint, and on that basis denies any and all other allegations in that paragraph.
- 18. SenoRx lacks information sufficient to form a belief as to Hologic's current activities and on that basis denies any and all allegations set forth in paragraph 18 of the Amended Complaint.
- 19. SenoRx admits that it submitted a premarket notification under section 510(k) of the Food, Drug and Cosmetic Act for a device for implementing breast brachytherapy, specifying the device name "SenoRad Multi-Lumen Balloon Source Applicator for Brachytherapy." The remaining allegations of paragraph 19 of the Amended Complaint set forth legal conclusions to which no response is required. To the extent that paragraph 19 of the Amended Complaint sets forth further factual allegations to which a response is required, SenoRx denies any and all other allegations set forth in paragraph 19 of the Amended Complaint.
- 20. SenoRx admits that the FDA approved its premarket notification on or about May 18, 2007. The section 510(k) summary (No. K071229), attached as Exhibit D to the Amended Complaint, speaks for itself. SenoRx denies that the MammoSite® Radiation Therapy System is

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claimed by the Patents-In-Suit, and denies any and all other allegations set forth in paragraph 20 of the Amended Complaint.

- 21. SenoRx admits that the MammoSite® Instruction Manual, under the heading Contraindications, states "Do not deliver radiation if the minimum distance from the balloon surface to the skin surface is less than 5 mm; or if the distance from the balloon surface to the skin surface is 5 mm over a continuous length greater than 1 cm on the surface of the skin." To the extent that paragraph 21 of the Amended Complaint sets forth further factual allegations to which a response is required, SenoRx denies any and all other allegations set forth in paragraph 21 of the Amended Complaint.
- 22. SenoRx admits that the MammoSite® Instruction Manual warns that "[i]maging should verify a minimum distance of 5 mm from balloon surface to skin surface; however, a minimum distance of 7 mm from balloon surface to skin surface is recommended." To the extent that paragraph 22 of the Amended Complaint sets forth further factual allegations to which a response is required, SenoRx denies any and all other allegations set forth in paragraph 22 of the Amended Complaint.
- 23. SenoRx denies any and all allegations set forth in paragraph 23 of the Amended Complaint.
- 24. SenoRx admits that it refers to the SenoRad device by, inter alia, the tradename "ConturaTM Multi-Lumen Balloon." To the extent that paragraph 24 of the Amended Complaint sets forth further factual allegations to which a response is required, SenoRx denies any and all other allegations set forth in paragraph 24 of the Amended Complaint.

ANSWER TO COUNT ONE – INFRINGEMENT OF U.S. PATENT NO. 5,913,813

- 25. In response to paragraph 25 of the Amended Complaint, SenoRx hereby incorporates its responses to paragraphs 1 through 24 of the Amended Complaint as if fully set forth herein.
 - 26. SenoRx denies the allegations set forth in paragraph 26 of the Amended Complaint.
 - 27. SenoRx denies the allegations set forth in paragraph 27 of the Amended Complaint.
 - 28. SenoRx denies the allegations set forth in paragraph 28 of the Amended Complaint.

- 29. SenoRx denies the allegations set forth in paragraph 29 of the Amended Complaint.
- 30. SenoRx denies the allegations set forth in paragraph 30 of the Amended Complaint.

ANSWER TO COUNT TWO – INFRINGEMENT OF U.S. PATENT NO. 6,413,204

- 31. In response to paragraph 31 of the Amended Complaint, SenoRx hereby incorporates its responses to paragraphs 1 through 30 of the Amended Complaint as if fully set forth herein.
 - 32. SenoRx denies the allegations set forth in paragraph 32 of the Amended Complaint.
 - 33. SenoRx denies the allegations set forth in paragraph 33 of the Amended Complaint.
 - 34. SenoRx denies the allegations set forth in paragraph 34 of the Amended Complaint.
 - 35. SenoRx denies the allegations set forth in paragraph 35 of the Amended Complaint.
 - 36. SenoRx denies the allegations set forth in paragraph 36 of the Amended Complaint.

ANSWER TO COUNT THREE - INFRINGEMENT OF U.S. PATENT NO. 6,482,142

- 37. In response to paragraph 37 of the Amended Complaint, SenoRx hereby incorporates its responses to paragraphs 1 through 36 of the Amended Complaint as if fully set forth herein.
 - 38. SenoRx denies the allegations set forth in paragraph 38 of the Amended Complaint.
 - 39. SenoRx denies the allegations set forth in paragraph 39 of the Amended Complaint.
 - 40. SenoRx denies the allegations set forth in paragraph 40 of the Amended Complaint.
 - 41. SenoRx denies the allegations set forth in paragraph 41 of the Amended Complaint.
 - 42. SenoRx denies the allegations set forth in paragraph 42 of the Amended Complaint.

ANSWER TO COUNTS FOUR, FIVE, AND SIX – FEDERAL AND STATE UNFAIR COMPETITION

43. Counts Four, Five, and Six of the Amended Complaint have been dismissed from this lawsuit, and accordingly no response is required for paragraphs 43-82 of the Amended Complaint. To the extent that these paragraphs set forth any allegations to which a response is required, SenoRx denies any and all allegations set forth in paragraphs 43-82 of the Amended Complaint.

ANSWER TO DEMAND FOR JURY TRIAL

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44. The allegations of paragraph 83 of the Amended Complaint set forth legal conclusions to which no response is required.

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ANSWER TO PRAYER FOR RELIEF

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45. The "WHEREFORE" paragraph following paragraph 83 of the Amended Complaint states Plaintiffs' prayer for relief to which no response is required. To the extent a response is required, SenoRx denies the allegations set forth in the "WHEREFORE" paragraph following paragraph 83 of the Amended Complaint and denies that Plaintiffs are entitled to any of the relief requested therein, or to any relief whatsoever.

AFFIRMATIVE DEFENSES

SenoRx sets forth the following affirmative and other defenses. SenoRx does not intend hereby to assume the burden of proof with respect to those matters as to which, pursuant to law, Plaintiffs bear the burden.

FIRST DEFENSE - NONINFRINGEMENT OF U.S. PATENT NO. 5,913,813

46. The manufacture, use, offer to sell, sale, and/or importation of SenoRx's products has not infringed, does not infringe, and will not infringe (either directly, contributorily, or by inducement, or by any theory of equivalency) any valid, enforceable claim of U.S. Patent No. 5,913,813 (the "'813 patent").

SECOND DEFENSE – NONINFRINGEMENT OF U.S. PATENT NO. 6,413,204

47. The manufacture, use, offer to sell, sale, and/or importation of SenoRx's products has not infringed, does not infringe, and will not infringe (either directly, contributorily, or by inducement, or by any theory of equivalency) any valid, enforceable claim of U.S. Patent No. 6,413,204 (the "'204 patent").

THIRD DEFENSE – NONINFRINGEMENT OF U.S. PATENT NO. 6,482,142

48. The manufacture, use, offer to sell, sale, and/or importation of SenoRx's products has not infringed, does not infringe, and will not infringe (either directly, contributorily, or by inducement, or by any theory of equivalency) any valid, enforceable claim of 6,482,142 (the "142 patent").

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FOURTH DEFENSE – INVALIDITY OF U.S. PATENT NO. 5,913,813

49. Each of the claims of the '813 patent is invalid for failure to satisfy the provisions of one or more of sections 101, 102, 103, 112, and/or 116 of Title 35 of the United States Code.

FIFTH DEFENSE – INVALIDITY OF U.S. PATENT NO. 6,413,204

50. Each of the claims of the '204 patent is invalid for failure to satisfy the provisions of one or more of sections 101, 102, 103, 112, and/or 116 of Title 35 of the United States Code.

SIXTH DEFENSE – INVALIDITY OF U.S. PATENT NO. 6,482,142

51. Each of the claims of the '142 patent is invalid for failure to satisfy the provisions of one or more of sections 101, 102, 103, 112, and/or 116 of Title 35 of the United States Code.

SEVENTH DEFENSE - UNENFORCEABILITY OF U.S. PATENT NO. 6,413,204 DUE TO **INEQUITABLE CONDUCT ('204 MISREPRESENTATION)**

- 52. Defendant incorporates by reference all of the foregoing allegations and averments of its answer and affirmative defenses.
- 53. Each of the claims of the '204 patent are unenforceable for inequitable conduct before the United States Patent and Trademark Office ("PTO").
- 54. The application that led to the issuance of the '204 patent was filed on April 15, 1999. The '204 patent issued on July 2, 2002.
- The attorneys responsible for prosecuting the application leading to the '204 patent 55. included Thomas J. Engellenner and Ronald E. Cahill, of the firm Nutter, McClennen & Fish LLP (collectively and individually the "204 prosecuting attorneys").
- During the examination of the '204 patent, while under a duty of candor to the 56. PTO, one or more of the named inventors, and, on information and belief, the '204 prosecuting attorneys and/or individuals at Proxima responsible for the prosecution of the application, engaged in inequitable conduct with intent to mislead the PTO in an effort to obtain the '204 patent.
- 57. Proxima, as assignee of the '204 patent, controlled and/or had knowledge of the prosecution of the '204 patent. Plaintiffs are accountable for the material misstatements and omissions made by Proxima, the inventors of the '204 patent, and/or the '204 prosecuting attorneys with intent to deceive the PTO.

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- On or about December 20, 2000, Proxima and the named inventors, through the 58. '204 prosecuting attorneys, made to the PTO the following statement (the "'204 misrepresentation"): "[S]ince compression of the brain tissue surrounding the outer balloon 28B (see Figure 7) might prove detrimental to the health of the patient, Applicant urges that Williams fails to disclose or teach an expandable surface element that is adapted to contact tissue surrounding the resected cavity and conform the tissue to the desired shape of the expandable surface element, as is recited in claims 4 and 28."
- The "Williams" reference discussed in the portion of the prosecution history quoted 59. in paragraph 58 refers to U.S. Patent No. 5,429,582, naming Dr. Jeffery A. Williams as the inventor (hereinafter the "Williams '582 patent").
- The Williams '582 patent was assigned to Proxima, a predecessor-in-interest to 60. Plaintiffs, some time prior to December 20, 2000.
- On or prior to December 20, 2000, one of the named inventors, the prosecuting 61. attorney(s), and/or some other individual with a duty of disclosure knew that devices of the type described in the Williams '582 patent could be adapted to contact tissue surrounding a resected cavity in the brain and adapted to conform the tissue to the desired shape of the expandable surface element.
- 62. On or prior to December 20, 2000, one of the named inventors, the prosecuting attorney(s), and/or some other individual with a duty of disclosure knew that devices of the type described in the Williams '582 patent were or could be adapted to conform brain tissue surrounding the outer balloon of the device without detriment to the health of a patient.
- 63. Plaintiffs and/or Plaintiffs' predecessor in interest, Proxima, have represented that the Williams '582 patent covers the GliaSite RTS device.
- One or more of the inventors of the '204 patent have represented that the Williams 64. '582 patent covers the GliaSite RTS device.
 - 65. The GliaSite RTS device is used in the brain to treat brain tumors.

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- 66. The GliaSite RTS device is adapted to contact tissue surrounding a resected cavity in the brain and adapted to conform the tissue to the desired shape of the outer balloon of the GliaSite RTS.
- 67. The GliaSite RTS device can be adapted to conform brain tissue surrounding the outer balloon of the device without detriment to the health of the patient.
- 68. The '204 misrepresentation was intended to mislead the PTO into believing that the Williams '582 patent fails to disclose or teach an expandable surface element that is adapted to contact tissue surrounding the resected cavity and adapted to conform the tissue when in fact it does.
- 69. The '204 misrepresentation was intended to mislead the PTO into believing that conformance of brain tissue by a device of the type disclosed by the Williams '582 patent would prove detrimental to the health of the patient when in fact it would not.
- 70. The '204 misrepresentation was known during the examination of the '204 patent to be materially false and misleading.
 - 71. The '204 misrepresentation violated the duty of candor owed to the PTO.
 - 72. The '204 misrepresentation was made with intent to deceive the PTO.
- 73. Plaintiffs may not enforce the '204 patent due to inequitable conduct during its prosecution.

EIGHTH DEFENSE - UNENFORCEABILITY OF U.S. PATENT NO. 6,482,142 DUE TO **INEQUITABLE CONDUCT ('142 MISREPRESENTATIONS)**

- 74. Defendant incorporates by reference all of the foregoing allegations and averments of its answer and affirmative defenses.
- 75. Each of the claims of the '142 patent are unenforceable for inequitable conduct before the United States Patent and Trademark Office ("PTO").
- 76. The application that led to the issuance of the '142 patent was filed on December 16, 1999. The '142 patent issued on November 19, 2002.
- 77. The attorneys responsible for prosecuting the application leading to the '142 patent included Thomas J. Engellenner and Ronald E. Cahill, of the firm Nutter, McClennen & Fish LLP (collectively and individually the "'142 prosecuting attorneys").

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- 78. During the examination of the '142 patent, while under a duty of candor to the PTO, one or more of the named inventors, and, on information and belief, the '142 prosecuting attorneys and/or individuals at Proxima responsible for the prosecution of the application, engaged in inequitable conduct with intent to mislead the PTO in an effort to obtain the '142 patent.
- 79. Proxima, as assignee of the '142 patent, controlled and/or had knowledge of the prosecution of the '142 patent. Plaintiffs are accountable for the material misstatements and omissions made by Proxima, the inventors, and/or the '142 prosecuting attorneys with intent to deceive the PTO. Plaintiffs may not enforce the '142 patent due to inequitable conduct during its prosecution.
- On or about December 16, 1999, Proxima, the named inventors, through the '142 80. prosecuting attorneys, filed the application that led to the '142 patent. The '142 application materially misrepresented the teachings of the Williams '582 patent in order to deceive the PTO examiner into believing that it was not material to the patentability of the '142 patent (the "'142 misrepresentations").
- 81. The '142 patent is directed to providing an asymmetric radiation dose to tissue through the use of an asymmetrically-placed radiation source.
- 82. In the application leading to the '142 patent, the named inventors, through the '142 prosecuting attorneys, made to the PTO the following misstatements that were known during the examination of the '142 patent to be materially false and misleading: "Williams provides a catheter having an inflatable balloon at its distal end that defines a distensible reservoir. . . . The balloon is then inflated by injecting a fluid having one or more radionuclides into the distensible reservoir via a lumen in the catheter. The apparatus described in Williams solves some of the problems found when using radioactive seeds for interstitial brachytherapy, but leaves some problems unresolved. The absorbed dose rate at a target point exterior to a radioactive source is inversely proportional to the square of the distance between the radiation source and the target point. As a result, where the radioactive source has sufficient activity to deliver a prescribed dose, say 2 centimeters into the target tissue, the tissue directly adjacent the wall of the distensible reservoir, where the distance to the radioactive source is very small, may still be overly 'hot' to the

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1	point where healthy tissue necrosis may result It is also desirable, at least in some		
2	applications, to provide these advantages while tailoring the radiation dosage to avoid fully dosing		
3	sensitive tissue or to reduce the amount of radiation that escapes the patient's body." '142 patent		
4	col. 2: 43-53.		
5	83. This statement was materially misleading in that it implies and states the Williams		

- This statement was materially misleading in that it implies and states the Williams 83. '582 patent has only a single balloon into which radioactive fluid is placed directly adjacent the tissue, but the Williams '582 patent actually discloses in Figure 7 a device having two balloons, the inner of which contains radioactive fluid, thus providing a space between the radiation source and the tissue.
- 84. The statement also was materially misleading in that it implies and states the Williams '582 patent does not provide for asymmetric delivery of radiation to tissue, where the Williams '582 patent actually discloses in Figure 7 a device which does deliver asymmetric doses of radiation to tissue.
- 85. Furthermore, the inventors of the '142 patent, through their attorneys, admitted during prosecution of the '204 patent that the device of Figure 7 of the Williams '582 patent delivered asymmetric doses of radiation to tissue, but did not inform the PTO of this fact during prosecution of the '142 patent.
- 86. The statements made during the prosecution of the '204 patent that are not consistent with the characterization of the '582 Patent in the Background section of the '142 Patent.
 - 87. The Williams '582 patent is material to the patentability of the '142 patent.
- 88. The Williams '582 patent was not disclosed to the Patent Office as required by 37 CFR 1.56.
- 89. The misrepresentations and omissions in the '142 patent application and its prosecution were intended to mislead the PTO.
- 90. The misrepresentations and omissions in the '142 patent application and its prosecution violated the duty of candor owed to the PTO.

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Plaintiffs may not enforce the '142 patent due to inequitable conduct during its 91. prosecution.

NINTH DEFENSE - UNENFORCEABILITY OF U.S. PATENT NO. 6,482,142 DUE TO **INEQUITABLE CONDUCT ('142 MATERIAL OMISSIONS)**

- 92. Defendant incorporates by reference all of the foregoing allegations and averments of its answer and affirmative defenses.
- Each of the claims of the '142 patent are unenforceable for inequitable conduct 93. before the United States Patent and Trademark Office ("PTO").
- The application that led to the issuance of the '142 patent was filed on December 94. 16, 1999. The '142 patent issued on November 19, 2002.
- The attorneys responsible for prosecuting the application leading to the '142 patent 95. included Thomas J. Engellenner and Ronald E. Cahill, of the firm Nutter, McClennen & Fish LLP (collectively and individually the "142 prosecuting attorneys").
- During the examination of the '142 patent, while under a duty of candor to the 96. PTO, one or more of the named inventors, and, on information and belief, the '142 prosecuting attorneys and/or individuals at Proxima responsible for the prosecution of the application, engaged in inequitable conduct with intent to mislead the PTO in an effort to obtain the '142 patent.
- 97. Proxima, as assignee of the '142 patent, controlled and/or had knowledge of the prosecution of the '142 patent. Plaintiffs are accountable for the material omissions made by Proxima, the inventors, and/or the '142 prosecuting attorneys with intent to deceive the PTO. Plaintiffs may not enforce the '142 patent due to inequitable conduct during its prosecution.
- 98. During the examination of the '142 patent, while under a duty of candor to the PTO, one or more of the named inventors, and, on information and belief, the '142 prosecuting attorneys had knowledge of material references that deliberately were not disclosed to the PTO ("the '142 concealed references"), in order to deceive the PTO.
- 99. The '142 concealed references include at least the Williams '582 patent; U.S. Patent No. 5,931,774 ("the '774 patent"); and R. D. Ashpole et al. 2 Clinical Oncology 333-37 (1990) ("Ashpole").

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> DEFENDANT SENORX, INC.'S ANSWER TO AMENDED COMPLAINT

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SENORX, INC.

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familiar with WSGR's practice for collecting and processing of correspondence for

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